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25 Transformative Years of Biosimilars

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2025 marks 25 years since India first ventured into the biosimilar space. Over the past quarter-century, the country has consistently solidified its position as a global leader in biosimilar approvals, with 135 approvals till January 2025. Initially focused on simpler biologics, the field now includes developing and approving complex monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), a diversified therapeutic focus, and a growing number of innovative players entering the field. As the industry celebrates this silver jubilee, we reflect on the journey that has not only transformed India's biotechnology sector but has also played a pivotal role in making life-saving treatments more accessible and affordable worldwide.

The first 'similar biologic' was approved and marketed in India for a hepatitis B vaccine in 2000, well ahead of the European Medicines Agency's (EMA) approval in 2006 and the United States Food and Drug Administration's (US FDA) approval in 2015 for biosimilars for export. Since then, the biosimilars landscape in India has grown leaps and bounds. As of January 2025, India has approved 135 biosimilars across various continents, far surpassing the approvals in the US FDA and EMA. The Indian biosimilars market was valued at approximately Rs 4.37 billion in 2024 and is expected to grow at a compound annual growth rate (CAGR) of 14.2 per cent, reaching around Rs 16.49 billion by 2034 as per Expert Market Research.

Talking about therapeutic trends, **Dr Cyrus Karkaria, President – Biotechnology at Lupin**, said, “Around 75 per cent of the biosimilars approved by Central Drugs Standard Control Organisation (CDSCO) are primarily used for cancer treatment and supportive care. Filgrastim, pegfilgrastim, rituximab, trastuzumab, and bevacizumab are some of the most commonly prescribed biosimilars in these fields. Other key therapeutic areas where biosimilars have made a difference include adalimumab, etanercept, and infliximab for autoimmune disorders like rheumatoid arthritis, as well as epoetin alfa and darbepoetin alfa for anaemia associated with chronic kidney disease. Ranibizumab biosimilars are transforming the treatment of wet age-related macular degeneration (AMD), while biosimilars of insulin glargine and recombinant human insulin are improving the accessibility and affordability of diabetes mellitus treatment. These cost-effective alternatives have significantly improved access to essential biologic therapies for patients across the country. However, there are still numerous unmet needs in disease areas such as asthma, allergy, dyslipidemia, and others, and India has the potential to address these requirements effectively.”

Indian companies are credited with many industry firsts. In 2013, Biocon, in partnership with Mylan, received approval for its trastuzumab biosimilar of *Herceptin*, the world’s best-selling breast cancer drug at the time, marking a major milestone in oncology biologics. Zydus Cadila, another frontrunner, became the first company to receive approval for a biosimilar of AbbVie’s *Humira*, the top-selling drug worldwide in 2014. In another breakthrough, Zydus also launched the world’s first biosimilar antibody-drug conjugate (ADC) — *Trastuzumab Emtansine* — for HER2-positive breast cancer in 2021.

Between 2000 and 2025, the big five Indian companies—Biocon, Intas, Dr. Reddy’s, Zydus, and Lupin—captured the lion's share of biosimilar approvals and launches. However, in recent years, smaller companies and emerging biotech firms have begun to make their mark, driving innovation and expanding the landscape of India’s biosimilars sector.

The Indian biosimilars that include vaccines, blood products, recombinant therapeutics (rDNA), stem cells and cell based products, landscape between 2000 and 2025 can be broadly categorised into two phases: the foundational period (2000–2013) and the accelerated growth phase (2014–2025). The early years were marked by approvals of relatively simpler biologics. The later phase saw the emergence of complex molecules such as monoclonal antibodies (mAbs), a more diversified therapeutic focus, and a significant increase in the number of companies entering the biosimilars space.

India has manufacturing capabilities of these biologics and also allowed multinationals to import and market in the country. The Central Drugs Standard Control Organisation (CDSCO) gave its first approval to Ethnor Limited to import and market r-hu-EPO in 1993 for Anaemia due to chronic renal failure. From 1993 to 2019 the CDSCO approved 197 biologics for import and marketing in the country. From 2020 till January 2025 another 104 biologics (r-DNA origin) received regulatory approval for marketing in India.

The Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment and Forestry responsible for appraisal of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle gave approvals for 38 recombinant therapeutics products for marketing in India.

The CDSCO has granted permission for manufacturing of 88 biologics from 2007- 2019 and 81 biologics from 2020 to January 2025 under MF and Bulk permission numbers. Wockhardt Limited got first approval for Insulin Glargine 100 IU on February 22, 2007 for the treatment of type -I and Type -II diabetes mellitus patients who required basal (long acting) insulin for the control of hyperglycemia.

Reflecting on the sector’s rapid progress, **Dr Sridevi Khambhampaty, CEO, Shilpa Biologicals** noted, “We’ve gone from just 1 per cent of eligible patients using biologics or biosimilars in the 2000s to around 40 per cent today. That number could rise to 60 per cent as more products from companies like Hetero, Enzene, MJ Pharma, and Shilpa Biologics enter the market.”

Let’s take a closer look at these past years in detail.

Tracing 25 Years of India’s Biosimilar Journey

2000-2010: The Foundational Years

The period from 2000 to 2010 marked the beginning of India's entry into the biosimilars space, with a series of first-time approvals for recombinant biologics across therapeutic areas.

The Indian biosimilars landscape began with Biovac-B for hepatitis B, led by Wockhardt, a critical first step in local biologics manufacturing. The early 2000s saw leading firms like Intas, Wockhardt, Dr. Reddy's, Gennova, and Reliance Life Sciences enter the space, focusing on recombinant hormones and growth factors.

Next approval came five years later, in August 2005, when Intas Pharmaceuticals received authorisation to market Epofit/Erykine, a biosimilar of epoetin alfa, for treating anaemia linked to cancer, chronic kidney disease, and chemotherapy. Another significant milestone occurred in February 2007 when Wockhardt obtained approval for Insulin Glargine (100 IU), marking one of India's earliest biosimilar approvals for a long-acting insulin analogue.

The year 2010 saw a sharp increase in the number of biosimilar approvals, with several companies entering the space. In March 2010, Dr. Reddy's Laboratories received approval for Darbepoetin alfa, a long-acting erythropoiesis-stimulating agent (ESA) used in the treatment of anaemia associated with chronic renal failure and chemotherapy. The product was cleared for use in both dialysis and non-dialysis patients, as well as in non-myeloid cancer patients receiving chemotherapy.

Gennova Biopharmaceuticals received approval for two granulocyte colony-stimulating factor (G-CSF) products: Pegfilgrastim in January and Filgrastim in March. Both were designed to prevent neutropenia in cancer patients undergoing chemotherapy, marking Gennova's entry into oncology supportive care.

In April 2010, Virchow Biotech Pvt Ltd. gained approval for a combination biologic—recombinant human PDGF-BB + ?-TCP, targeted at treating periodontal defects like intrabony defects and gingival recession, standing out in regenerative dentistry applications. Reliance Life Sciences Pvt Ltd. also received approval for recombinant human follicle-stimulating hormone (r-hu-FSH) to treat female infertility.

Cadila Healthcare Ltd. (Zydus) followed with the approval of r-hu-EPO lyophilised injection, indicated for maintaining haemoglobin levels in patients with chronic renal failure.

Closing out the year, Intas Biopharmaceuticals secured approval in November 2010 for Teriparatide [r-hu-Parathyroid Hormone (1-34)], a biosimilar used in postmenopausal women with osteoporosis who are at high risk for fractures. This represented one of the earliest biosimilar entries into the osteoporosis segment in India.

Altogether, India approved 10 biosimilars across key therapeutic areas such as nephrology, endocrinology, reproductive health, and bone metabolism.

2011-2015: The Boom Phase

This period was marked by several key milestones. In 2012, India introduced its biosimilar policy, laying the foundation for a more structured regulatory environment. In 2013, Biocon, in partnership with Mylan, received approval for its trastuzumab biosimilar to Herceptin, the world's best-selling breast cancer drug. In 2014, Zydus Cadila became the first company to receive approval for a biosimilar of AbbVie's Humira, the world's top-selling drug at the time.

The formalisation of CDSCO's biosimilar evaluation process in 2012 helped improve regulation. Between 2011 and 2015, India saw a sharp rise in biosimilar activity, with 44 approvals.

A notable trend in this period was the increasing number of complex biologics like trastuzumab, rituximab, and adalimumab entering the Indian market, indicating growing capabilities in monoclonal antibody production. Among all molecules, filgrastim emerged as the most commonly approved biosimilar across different manufacturers—Lupin, Cadila, and Hetero Drugs.

Most approvals targeted prevalent conditions in India:

- Oncology: Trastuzumab, rituximab, and later, bevacizumab.
- Autoimmune Diseases: TNF inhibitors like etanercept and adalimumab.
- Haematology: Filgrastim, epoetin for anaemia and neutropenia.

2016-2020: Evolving regulations and expansion into international markets

The glory days of previous years continued into this period, marked by several important milestones for Indian companies and the country's biosimilar space in general.

In 2016, Biocon's Insulin Glargine became the first biosimilar from India to be commercialised in Japan. In December 2017, Ogivri, a biosimilar of Trastuzumab co-developed by Biocon and Mylan, became the world's first biosimilar of Herceptin to be approved in the US. In 2018, Fulphila (Pegfilgrastim), another biosimilar co-developed by Biocon and Mylan, became the first biosimilar of Neulasta to be approved in the US.

In 2016, the CDSCO revised its guidelines, providing clearer regulations for biosimilars, which helped streamline the approval process. From 2016-2020, India saw over 25 biosimilar approvals across various therapeutic areas, including oncology, immunology, and nephrology. These approvals were for both monoclonal antibodies and other biologics, marking a significant increase in India's biosimilar market activity. Companies such as Reliance Life Sciences, Intas Pharmaceuticals, Hetero Drugs, and Dr. Reddy's Laboratories were key players in bringing these therapies to market.

Bevacizumab emerged as a frequently approved biosimilar, with multiple companies launching versions for colorectal cancer, lung cancer, and ovarian cancer. Pegfilgrastim, adalimumab, and etanercept were also prominent, with approvals for treating conditions like chemotherapy-induced neutropenia, rheumatoid arthritis, and psoriasis. The sector continued to grow, with the approval of biosimilars for more specialised conditions such as chronic kidney disease, macular degeneration, and chronic urticaria.

2021-2025: Diversification and push toward global standards

From 2021 to 2025, India's biosimilar industry continued to build on the momentum of previous years, experiencing rapid growth. During this period, 56 approvals were granted, with significant advancements in oncology, autoimmune diseases, ophthalmology, diabetes care, and rare conditions. This phase also saw the emergence of newer players such as Enzene Biosciences, Shilpa Biologicals, etc.

The therapeutic dominance of oncology and autoimmune conditions continued, with recurring approvals for *trastuzumab*, *bevacizumab*, *adalimumab*, and *rituximab* from both new entrants and legacy players. India also ventured into rare and niche therapies, with Trinbelimab for maternal health, marking a new frontier for biosimilars in specialised fields. Several companies secured approvals for updated formulations, additional indications, or second-generation biosimilars of earlier-approved molecules, demonstrating maturing portfolio strategies.

What next?

The impending patent cliff presents a significant opportunity for biosimilar companies worldwide. Between 2025 and 2032, 39 high-value biologics are set to lose patent exclusivity. Five of these molecules generate over $10 billion each in global annual revenues, creating a substantial opening for Indian biosimilar manufacturers. Indian companies are gearing up to capture a larger piece of this pie. Many top firms are investing heavily in R&D, expanding their manufacturing capacities, and building robust product pipelines, with over 40 biosimilars currently in development, according to Bain & Company. However, it won't be without challenges. India faces stiff competition from China and South Korea, which are leading in US FDA biosimilar approvals.

India has built a robust domestic biosimilars market, but its international presence remains limited. Dr Cyrus Karkaria points out that progress in global markets has been relatively slow.

"Of the biosimilars manufactured by Indian companies, approximately 17 have received approval in Europe, while only 9 have been approved in the US," he noted.

As a result, India's share in the global biosimilars market remains modest. Indian pharmaceutical firms currently hold less than 5 per cent of the global market, with biosimilar exports valued at approximately $0.8 billion as per Bain and Company.

It doesn't help that some experts feel that the CDSCO has taken a lenient approach to biosimilar approvals. There are concerns that misalignment between CDSCO and FDA/EMA on clinical trial requirements for biosimilars may also hinder

domestic manufacturers from participating on a global scale. That said, reforms are underway. The Drug Controller General of India (DCGI) has indicated that revised biosimilar guidelines will soon be released, aiming to align India's regulatory framework with global standards. The Indian government is also pushing forward with public initiatives like the National Biopharma Mission and PLI schemes to bolster the sector.

Indian companies are also scaling up—investing in R&D, expanding manufacturing capacity, and forging strategic partnerships to strengthen their global presence. In June 2024, Aurigene Pharma announced the opening of a new biologics facility in Genome Valley, marking a significant step toward building world-class infrastructure. In July 2025, Mankind Pharma revealed its plan to acquire Bharat Serums and Vaccines from Advent International for Rs13,630 crore. On the collaboration front, several global tie-ups have been announced. In February 2025, Dr. Reddy's Laboratories inked a licensing deal with China's Henlius for HLX15, an investigational daratumumab biosimilar, targeting expansion in Europe and the U.S. In March 2025, Dr. Reddy's also partnered with Bio-Thera to extend its biosimilar footprint across Southeast Asia.

Looking ahead, experts are bullish about India's potential to take on a larger role in the global biosimilars market.

"Leveraging its strengths in developing cost-effective Biosimilars, India is well poised to become a key player in the global biosimilar Industry. Indian biosimilar exports are currently valued at ~$0.8 billion and projected to grow fivefold to $4.2 billion by 2030, and reach $30-35 billion by 2047. Key factors driving growth in exports include global trends such as the simplification of biosimilar approval pathways in the US and Europe, including interchangeability, extrapolation of Indications and waiver on phase 3 clinical trials. In addition, Indian manufacturers have already embarked on building world class manufacturing facilities and generating value through CDMOs, where just like generics, we would be the high quality and affordable biosimilar producers for the world Navigating through regulatory complexities, fostering collaboration with global pharmaceutical companies and leveraging technology will be the key to advancing R&D and achieving leadership in global biosimilar space," said Dr Karkaria.

Dr Sridevi echoes similar sentiments, "Again in a few words I would say 'growing massively'. We now have some 25 years of pedigree in developing and launching these therapies, and therefore a very well-trained workforce with an excellent understanding of global requirements. This, coupled with recent proposed changes to biosimilar regulations globally [waiving phase 3 studies], means we are potentially removing the large investment barrier required for new approvals. Therefore, it will open-up opportunities to develop biosimilars for indications which previously required large and expensive phase 3 studies (like antibodies for migraine etc.). So my view is that India will be contributing at least 15-20 per cent of global biosimilars moving forward – especially if we can leverage the opportunity of the new regulatory paradigm."

The first 25 years of India's biosimilar journey focused on building domestic capacity and regulatory frameworks. The next 25 years will centre on global expansion. With growing expertise and shifting geopolitical dynamics, Indian biosimilar companies are poised to seize a bigger piece of the pie. The next 25 years are set to be Bharat's biosimilar moment on the world stage.

India's Biosimilars Revolution

Alex Del Priore, Senior Vice President – Manufacturing, Syngene International

The increasing incidence of chronic illnesses such as cancer, diabetes, and autoimmune disorders, which necessitate long-term biologic therapies, is driving the growth of the biosimilar market in India. Since introducing the "Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India" in 2012, which was later revised in 2016, the Indian biosimilar industry has made significant strides. With a robust pharmaceutical sector, India is now a leader in biosimilar production, boasting approximately 100 domestically approved biosimilars. Several Indian companies have also received approval for Biosimilars in the US and Europe. Indian companies have catered to the local market and emerged as global frontrunners in biosimilars, playing a crucial role in enhancing the accessibility of biological therapies.

Biosimilars are notably impacting various therapeutic areas in India, particularly in oncology, autoimmune disorders, and diabetes. In the oncology sector, biosimilars such as Trastuzumab, Bevacizumab, Rituximab, and Cetuximab are effectively treating a substantial patient population across multiple cancer types. Additionally, there is a robust pipeline of biosimilars in the oncology field. For Rheumatoid Arthritis, biosimilars for Etanercept and Adalimumab have been approved, expanding treatment options for many patients. The introduction of biosimilar insulins in the Indian healthcare landscape is crucial for improving access to insulin for all diabetes patients. The growing availability of insulin biosimilars is expected to enhance accessibility and potentially reduce costs for individuals with diabetes. Furthermore, several other biosimilars have been approved for conditions such as neutropenia, anemia, and multiple sclerosis. These cost-effective alternatives significantly improve access to vital biologic therapies for patients nationwide.

Biosimilars hold a substantial share of the Indian pharmaceutical market, and this sector is witnessing impressive growth, indicating a bright future ahead. But at the same time, India must innovate. Stronger regulations and more R&D spending will enable India to keep offering reasonably priced biologic treatments to millions of people worldwide, guaranteeing that biosimilars will continue to play a significant role in healthcare in the future.

Ayesha Siddiqui